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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/657,749	05/30/1996	JAMES G. METZ	CGNE-101-2	2351

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/11/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	08/657,749	METZ ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 29* is/are pending in the application.

4a) Of the above claim(s) *,7-10 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 11-13, and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth:

> § 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;
>
> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers: In the specification; page 40 line 17, page 50 line 23, page 56 lines 18-23, page 59 lines 22, page 78 line 31, page 79 line 22, page 80 line 6, page 81 lines 13, 21; Claims 5-6 (CE15 class and CE20 class); and throughout the drawings.

Election/Restrictions

Applicant's election with traverse of Group I, and species election of claims 4-6, in Paper No. 25 is acknowledged. The traversal is on the ground(s) that there would be no undue burden in examining Groups I-II together and that up to ten sequences are permitted per MPEP 803.04. This is not found persuasive because the methods of Groups I-II are drawn to unique DNA compositions of discrete function. The prior indication, in 1996, that up to ten sequences were permissible was meant to apply to EST sequences, rather than promoters or coding sequences. Furthermore, since 1996 resources at the Patent office have charged, and the examination and search of more than one sequence would pose an undue burden. Finally, one sequence constitutes "up to ten".

The requirement is still deemed proper and is therefore made FINAL.

Applicant's earliest claimed priority is to parent application 07/796256 filed 11/20/1991 that is drawn to a polynucleotide sequence encoding a polypeptide having a fatty alcohol acyltransferase wax synthase activity. The instant application is drawn to a polynucleotide encoding a polypeptide having a ß-ketoacyl-CoA synthase activity, which was first disclosed in parent application 08/265,047 filed 06/23/1994 now issued U.S. Patent 5,679,881. Accordingly, the effective filing date of the instantly claimed invention is 23 June 1994.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 11-13, and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a very long chain fatty acid molecule-altering DNA sequence, a ß-ketoacyl-CoA synthase DNA sequence, and a polynucleotide encoding a CE15 class and CE20 class of condensing enzyme.

Applicant describes a polynucleotide encoding a jojoba ß-ketoacyl-CoA synthase condensing enzyme (page 8 Table 8 refers to figure 3) and isolated cDNA clones from *Arabidopsis* of unspecified activity, CE15 and CE20 (page 8 Table 8 refers to figures 8-10), that

were amplified using degenerate PCR primers, and that have 50% homology to the jojoba condensing enzyme cDNA clone.

Applicant does not describe any other very long chain fatty acid molecule-altering DNA sequences other than a polynucleotide encoding a jojoba ß-ketoacyl-CoA synthase condensing enzyme (page 8 Table 8 refers to figure 3), and the putative CE15 and CE20 cDNA.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Given the failure of the very long chain fatty acid molecule-altering DNA sequences, ß-ketoacyl-CoA synthase cDNA, and the CE15 and CE20 sequences from *Arabidopsis* to be adequately described, methods of their use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111.

Claims 1-6, 11-13, and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for production of 24:1 VLCFA from above 5% to 7.8% of weight in seeds of canola transformed with a polynucleotide encoding jojoba ß-ketoacyl-CoA synthase condensing enzyme, does not reasonably provide enablement for production of 24:1 VLCFA above 5% or 7% in any other plant using any other very long chain fatty acid molecule-altering DNA sequences from canola or any other species encoding any of the condensing enzymes of either the C15 or C20 class. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a method for the production of 24:1 VLCFA in plants transformed with a very long chain fatty acid molecule-altering DNA sequence or either a CE15 or CE20 polynucleotide sequence encoding a condensing enzyme.

Applicant teaches a method for production of 24:1 VLCFA from above 5% to 7.8% of weight in seeds of transformed canola using the polynucleotide encoding jojoba ß-ketoacyl-CoA synthase condensing enzyme (Example 11 entry 14 in Table 7 on page 72).

Applicant does not teach a method for production of 24:1 VLCFA from above 5% weight in seeds of plants transformed with any other very long chain fatty acid molecule-altering DNA sequence or either a CE15 or CE20 polynucleotide sequence from *Brassica* encoding a condensing enzyme.

The isolation of orthologous DNA sequences from other species introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable either PCR amplification or southern hybridization and would entail using

either degenerate primers or probes with limited homology. Thus the screen for orthologous sequences would isolate many genes other than those of interest. The inherent unpredictability in isolation of a homologous sequence encoding the same protein activity is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and that a small number of changes to the coding region of a desaturase could account for the functional divergence seen across a range of enzymes involved in fatty acid metabolism (Broun P. *et al.* Science Vol. 282; 13 November 1998, pp. 1315-1317; Abstract lines 4-6 and p. 1317 column 1, lines 37-56).

Further, the transformation of *Arabidopsis* HEAR and LEAR plants with a jojoba cDNA encoding a ketoacyl-CoA synthase condensing enzyme resulted in no T2 transgenic plants having above 5% by weight 24:1 levels, and only one line of a cross between a transgenic LEAR and a HEAR control plant showed only 7.8% by weight 24:1 (Lassner M. *et al.* The Plant Cell, February 1996; Vol. 8; pp. 281-292; on page 283 Table 1). The authors further admit that a BLAST search of the dBEST database using the jojoba KCS cDNA aligned with cDNA related by homology to rice and *Arabidopsis* cDNA encoding enzymes of unknown function (See page 284 column 1, lines 1-5).

Moreover the usefulness of any broad claim to a specific utility for production of 24:1 VLCFA based upon homology to sequences from other species can be problematic. Two populations of *Arabidopsis* transformed with cDNA sequences related by homology and believed to have the same activity showed that a jojoba KCS enzyme made VLCFA of longer chain length than an FAE1 enzyme from *Arabidopsis* wherein the transgenic plants transformed with a gene

encoding the latter had levels similar to wild type and the *fae1* mutant (Millar A. *et al.* Plant Journal. 1997; Vol. 12; No. 1; pp. 121-131; page 127).

Given the lack of guidance for isolating any other very long chain fatty acid molecule-altering DNA sequence that would produce 24:1, or for methods of producing plants transformed with said sequences showing levels of 24:1 of 5% by weight or higher, the breadth of the claims, and given the unpredictability in the art, undue trail and error experimentation would be needed by one skilled in the art to isolate a multitude of non-exemplified very long chain fatty acid molecule-altering DNA sequences that would produce 24:1, or to evaluate the ability of a multitude of non-exemplified very long chain fatty acid molecule-altering DNA sequence that would produce 24:1 to alter the phenotype of a multitude of transformed plant species. Therefore, the invention is not enabled for the scope set forth in the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 11-13, and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 5,679,881. Although the conflicting claims are not identical, they are not patentably distinct

from each other because Claim 2 of the issued patent is drawn to the production of VLCFA encompassing the method of Claim 1 and the method steps of Claim 29 of the instant application, thus teaching the method for altering the composition of fatty acids in a plant cell.

Claims 1-3, 11-13, and 29 are deemed free of the prior art given the failure of the prior art to teach or suggest a method for the production or alteration of VLCFA in a plant seed cell or plant embryo cell.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
February 12, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638